FORA COMFORT check G40 Blood Glucose Test Strip User Manual

FORA COMFORT check G40 Blood Glucose Test Strip

Contents

Warnings

- For in vitro diagnostic use (for use outside of the body only).
- For single use only.
- Healthcare professionals and other users testing multiple patients with this system should handle everything that has come into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- Please read this sheet and your Blood Glucose Monitoring System Owner's Manual before you use this test strip. Use only FORA Test Strips with FORA Blood Glucose Monitoring System to obtain accurate results, and be covered by the manufacturer's warranty.
- Results may be inaccurate when testing on patients with abnormally low blood pressure or those who are in shock.
- Please do not use FORA Blood Glucose Monitoring System on critically ill patients. While the blood glucose result is extremely hyperglycemia (over 600 mg/dL (33.3 mmol/L)), the collection of capillary blood from the approved sample sites is not advised when the peripheral circulation is impaired as the delivery of physiological blood glucose level might not be a true reflection. The following circumstances may apply: severe dehydration as a result of diabetic ketoacidosis or due to stress hyperglycemic, hyperosmolar non-ketotic coma, shock, decompensated heart failure NYHA Class IV or peripheral arterial occlusive disease.
- Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

Intended Use

FORA test strips, when used together with FORA Blood Glucose Monitoring System, allow your blood glucose levels to be measured by yourself at home or by healthcare professionals. It uses fresh whole blood samples from the finger, and the following areas: the palm, forearm and upper arm. This system is not intended for use in the diagnosis or screening of diabetes mellitus.
Professionals may test with capillary and venous blood sample; home use is limited to capillary whole blood testing. Use only heparin for anticoagulation of whole blood.

Please do NOT use EDTA for anticoagulation.

Limitations

- Hematocrit: The hematocrit level is limited to between 35% and 60%. Please ask your healthcare professional if you do not know your hematocrit level.
- Neonatal Use: **This test strip must not be used for the testing of newborns.**
- Please see Appendix: Summary of substances and concentrations in excess of limitation with interference.
- Altitude Effects: Altitudes up to 3,275 m (10,742 ft) do not affect test results.
- Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can produce elevated glucose results

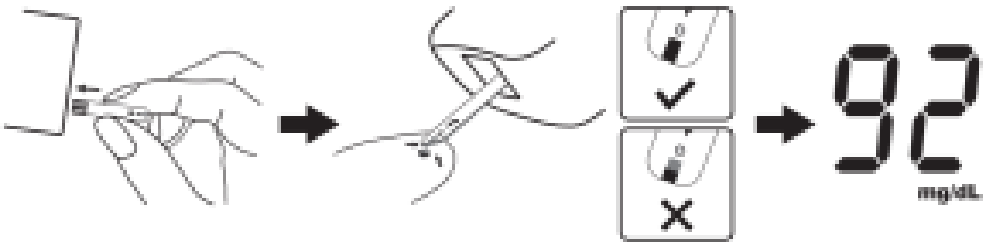
Storage and Handling

IMPORTANT: Do not use the test strips if they have expired.

► Test strips expire 6 months after first opening. Write the first opening date on the test strip vial when you first opened it.
► Store the test strips in a cool, dry place between 2°C and 30°C (35.6°F and 86°F) and below 85% relative humidity.
► Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
► Store the test strips in their original vial ONLY. Do not transfer them to a new vial or any other containers.
► Do not touch the test strips with wet hands.
► Use each test strip immediately after taking it out of the vial. Close the vial immediately after taking out a strip.
► Keep the vial closed at all times.
► Do not bend, cut, or alter the test strip.

Testing Your Blood Glucose

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTS.



Please refer to your Owner’s Manual for more information.

The used lancet and test strip are potentially biohazardous. Please dispose of them carefully according to your local regulations.

Reading Your Result

Your blood glucose readings deliver plasma equivalent results and are displayed in mg/dL or mmol/L.

Reference values

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meal	< 100 mg/dL (5.6 mmol/L)
2 hours after meals	< 140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association (2012). Clinical Practice Recommendations. Diabetes Care, 35 (Supplement 1): S1-100.

Please consult your doctor to determine a target range that works best for you.

Questionable or inconsistent results

If your test results are unusual or inconsistent with how you are feeling:

- Make sure the confirmation window of the test strip is completely filled with blood.
- Check the expiry date of the test strips.
- Check the performance of your meter and test strip with the control solutions.

Please Note: Unusually high or low blood glucose levels may be symptoms of a serious medical condition. If most of your results are unusually high or low, please contact your healthcare professional.

Quality Control Testing

Our control solutions contain a known amount of glucose that can react with test strips.
You can check the performance of the meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial. Checking regularly can ensure your test results are accurate. Please refer to the Owner's Manual for complete testing instructions.

IMPORTANT: The reference range of the control solutions may vary with each new test strip. Make sure you check the range on the label of vial or individual foil pack of your current test strip.

Chemical Components

> Glucose dehydrogenase (E. coli) 8%
> Electron shuttle 55%
> Enzyme protector 8%
> Non-reactive ingredients 29%

Additional Information for Healthcare Professionals

Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only. Professionals may use test strips to test capillary and venous whole blood.
Sample Size: 0.7 µL
Reaction Time: 7 seconds
System Measurement Range: 20 mg/dL to 600 mg/dL

Hematocrit Range: 35% to 60%

Accuracy

The table below displays how often FORA G40 achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well FORA G40 performed compared to YSI-2300 reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28 mmol/L)	Within ±10 mg/dL (Within ±0.55 mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
60.6% (181/294)	90.1% (265/294)	100% (294/294)

Table 2 Accuracy results for glucose concentration≧100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %*
49.7% (331/666)	81.7% (544/666)	96.4% (642/666)

Table 3 Accuracy results for glucose concentrations between 32.4mg/dL (1.80mmol/L) to 532.0mg/dL (29.56mmol/L)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
97.5% (936/960)

Note: *Acceptance criteria in EN ISO 15197: 2015 95% of all differences in glucose values (i.e., YSI-2300 reference values minus glucose values of FORA G40) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L). When Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while those above 100 mg/dL (5.55 mmol/L) are in percent.

User performance

160 subjects tested on the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how well FORA G40 performed compared to YSI-2300 reference method results.

Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	**Difference within ±5mg/dl**	**Difference within ±10mg/dl**	**Difference within ±15mg/dl**
Fingertip	26/45 (57.8%)	38/ 45 (84.4%)	45/ 45 (100%)
Palm	27/42 (64.3%)	41/42 (97.6%)	42/ 42 (100%)
Forearm	31/42 (73.8%)	39/42 (92.9%)	42/ 42 (100%)
Upper arm	29/42 (69.0%)	38/42 (90.5%)	41/42 (97.6%)

Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5%	Difference within ±10%	Difference within ±15%
Fingertip	61/115 (53.0%)	95/115 (82.6%)	115/115 (100%)
Palm	49/118 (41 .5 %)	92/118 (78.0%)	118/118(100%)
Forearm	43/118 (36.4 %)	84/118 (71 .2 %)	115/118 (97.5%)
Upper arm	49/118 (41 .5 %)	87/118 (73.7%)	116/118 (98.3%)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 5 mg/dL (0.28 mmol/L) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

Use only with **FORA COMFORT check G40** Blood Glucose Monitoring System

Appendix

Table A summarized the substances tested at recommended concentrations which bias is less than 10% and demonstrated no interference with FORA Test Strip.

Substance	Therapeutic/Physiologic Concentration Range (or Upper Lim it) {mg/dL)*	Concentration Tested {mg/dL)*
Cholesterol	300	500
Creatinine	1.7	30
Gent isic Acid	0.2 – 0.6	2
Hemoglobin (HemolysisMethod)	2.5	500
Heparin (Li)	35 – 100 U/dL	6800 U/ dL
Heparin (Na)	35 – 100 U/dL	6800 U/ dL
K2EDTA	180	702
K3EDTA	175.5	702
Ibuprofen	1-7	55
Icodextrin	1200	2000
Maltose	N/A	1000
Salicylic Acid	10- 30	60
Tolbutamide	4.32 – 24	64

Table B summarized the substance concentrations at which interference with glucose measurement was greater than ± 10% bias compared to the control test

Substance	Limiting Concentration (mg / dL)	Therapeutic/Physiologic Concentration Range (or Upper Limit) (mg/dL)
Acetaminophen (Paracetamol)	> 6.25	0.45 – 3
Ascorbic acid	> 5.0	2.0
Bilirubin (Unconjugated)	> 20	0-2
Dopamine	> 1.25	0.03
Levo – Dopa	> 0.7	0.02 – 0.28
Methyl-Dopa	> 1.875	0.1 – 0.5
Reduced Glutathione	> 30	24.25 – 32.2
Tolazamide	> 12.5	2 – 2.5
Uric acid	> 10	2-8
Xylose	> 3.125	N/A
Lipemic Samples (Triglycerides)	> 3000	30 – 300
Galactose	> 250	<5

Table C Summary of anticoagulant and concentrations with interference.

Substance	Limiting Concentration (mg/dL)	Concentration of Blood Drawing Tube (mg/dL)
Na-Fluoride/K-Oxalate	< 250/200	250/200

Table D The following compounds may produce elevated glucose results within the therapeutic or physiologic concentration range

Substance	Concentration Tested (mg/dL)	Therapeutic Concentration Range (or Upper Limit)(mg/dL
Pralidoxime Iodide	> 5.0	~ 10 (i.v. Dose 500 mg)

Reference

[1] McEnroe, J Robert, et al. National Committee for Clinical Laboratory Standards. Interference testing in clinical chemistry; Approved Guideline – 2nd edition. NCCLS : 2005 – EP7-A2, volume 25, number 27.
[2] EN ISO 15197: 2015 (E): In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, Second edition, section 6.4.4 Interference Testing, pp, 28-30.
[3] Hardman JG, Limbird LE, Molinoff PB, et al. Goodman & Gilman's the Pharmacological Basis of Therapeutics. 9th ed. New York, NY: McGraw-Hill; 1996: 1570-1571.
[4] Zaloga GP, Macgregor D. The Critical Care Drug Handbook. 2nd ed. St Louis, MO: Mosby-Year Book; 1997.
[5] Kost GJ, Vu HT, Lee JH, et al. Multicenter study of oxygen-intensive handheld glucose point-of-care testing in critical care/hospital/ambulatory patients in the United States and Canada. Crit Care Med. 1998; 26: 581-590.

Symbol	Referent/Signification
	• For in vitro diagnostic use
	• Do not reuse
	• Consult instructions for use
	• Temperature limitation

	• Use by
	• Keep dry
	• Keep away from sunlight
	• CE mark
	• Batch code
	• Humidity Limitation
	• Do not use if package is damaged
	• 6 months remain after first open
	• Manufacturer
	• Model number
	• Quantity

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Documents / Resources

	FORA COMFORT check G40 Blood Glucose Test Strip [pdf] User Manual COMFORT check G40, Blood Glucose Test Strip
	FORA Comfort Check G40 Blood Glucose Test Strip [pdf] Instruction Manual 312-4270400-004, Comfort Check G40 Blood Glucose Test Strip
	FORA COMFORT check G40 Blood Glucose Test Strip [pdf] Owner's Manual COMFORT check G40, Blood Glucose Test Strip, Glucose Test Strip, Test Strip

References

- ForaCare Suisse AG - Comprehensive Disease Management Solutions